PURPOSE: The Washington State Board of Health established the Immunization Advisory Committee (IAC) in December 2005 to recommend criteria the Board could use to determine which vaccines should be required for childcare center and/or school entry.

RATIONALE: Many new vaccines for children and young adults are expected to be available over the next few years. A number of these vaccines will end up on the Advisory Committee on Immunization Practices (ACIP) *Recommended Childhood and Adolescent Immunization Schedule*. The board will face complex decisions about which vaccines should be required in Washington State. Factors other than those considered by the ACIP will need to be considered to address the unique needs of our state. The Board believes that approaching this decision using rational criteria is the best method for protecting children and the community at large while balancing the interests of parents and families.

WHO: Immunization stakeholders from the fields of public health, school health, medicine, child advocacy, and medical ethics as well as consumers (parents) used consensus to identify the best criteria for determining which vaccines to require.

RESULTS: The IAC met three times to develop the recommendations described in this report. In addition, between the second and third meeting of the IAC a Technical Advisory Group (TAG) further refined the criteria and tested them against the pertussis antigen. The TAG comprised representatives from the fields of public health, primary care, epidemiology, and medical ethics. The IAC reviewed and further refined the TAG's work at its final meeting in March 2006.

Framework for Establishing the Criteria

John Stuart Mill in *On Liberty* wrote that "The only purpose for which power can rightfully be exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant." This thesis has become known as the harm principle. The Immunization Advisory Committee endorsed the harm principle and interpreted it to mean that vaccine mandates are justifiable when without them:

- An individual's decision could place others' health in jeopardy
- The state's economic interests could be threatened by the costs of care for vaccine preventable illness, related disability, or death, and by the cost of managing vaccine preventable disease outbreaks
- The state's duty of educating children could be compromised

Assumptions for Establishing the Criteria

The IAC made two assumptions while drafting criteria: (1) some kind of process exists for exemption from mandated immunization requirements; and (2) that mandated vaccine(s) with the antigen are accessible to those for whom it is mandated and cost is not a barrier. (Under the current system of universal purchasing, this would mean that the state purchases and distributes the vaccine.)

Review and Approval Process for Antigens in Vaccines required for School and/or Child Care Center Entry

1. The Board reviews the proposed antigen to determine whether the two assumptions listed above have been met, whether there is adequate information specific to Washington State with which to evaluate the antigen against the nine criteria below, and whether there is some likelihood, based on a preliminary review, that the antigen might meet those criteria.
2. If the Board determines that these preconditions have been met, the Board sponsor will establish a Technical Advisory Group (TAG) to review the antigen against the nine criteria. The TAG must include representatives from the fields of public health, primary care, epidemiology, and medical ethics. At the discretion of the board sponsor either a wider IAC or a TAG sub-committee can be formed (this expanded body could also include consumers [parents] and representatives from the fields of school health, school administration, child care, child advocacy, immunization administration, and others) to also participate in the review. The Board will ask DOH for any current information and data specific to Washington State that would be available from the Immunization Program or the Vaccine Advisory Committee and provide it to the TAG for consideration.
3. The TAG formulates a recommendation to the Board on whether it should initiate formal rule making that could result in the antigen being required for school and/or child care center entry. The TAG's recommendation will include a brief summary of the TAG's deliberations on each of the nine criteria.
4. These results are presented to the Board for its consideration and possible action.

The Three Categories of Criteria

The IAC grouped criteria into three categories: vaccine effectiveness, disease burden, and implementation. If a vaccine is a combination vaccine that contains more than one antigen, each antigen must be considered separately against the criteria.

Nine Criteria to Consider in Evaluating Antigens

I. Criteria on the effectiveness of the vaccine

1. *A vaccine containing this antigen is recommended by the Advisory Committee on Immunization Practices and included on its recommended childhood immunization schedule.*
2. *The antigen is effective in terms of population-based prevention.*
3. *The vaccine containing this antigen is cost effective (from a societal perspective).*
4. *Experience to date with the vaccine containing this antigen indicates that it is safe and has an acceptable level of side effects.*

II. Disease Burden Criteria

5. *The vaccine containing this antigen prevents diseases with significant morbidity and/or mortality implications (in some sub-set of the population).*
6. *Vaccinating the infant, child, or adolescent against this disease reduces the risk of person-to-person transmission.*

III. Implementation Criteria

7. *The vaccine is acceptable to the medical community and enjoys a high degree of public trust.*
8. *The administrative burdens of delivery and tracking of vaccine containing this (these) antigen(s) are reasonable.*
9. *The burden of compliance for the vaccine containing this antigen is reasonable for the parent/caregiver.*

Explanations for the Nine Criteria

I. *Criteria on the effectiveness of the vaccine*

1. *A vaccine containing this antigen is recommended by the Advisory Committee on Immunization Practices and included on its recommended childhood immunization schedule.*

   The vaccine must have been recommended by the Advisory Committee on Immunization Practice (ACIP). The ACIP reviews licensed vaccines, and makes recommendations for newly licensed vaccines and regularly updates its recommendations. Their process includes: (1) a review of the Food and Drug Administration (FDA) labeling/package inserts for each vaccine; (2) a thorough review of the scientific literature (both published and unpublished, when available) on the safety, efficacy, acceptability, and effectiveness of the immunizing agent, with consideration of the relevance, quality, and quantity of published and unpublished data; (3) an assessment of cost effectiveness; (4) a review of the morbidity and mortality associated with the disease in the

population in general and in specific risk groups; (5) a review of the recommendations of other groups; and (6) a consideration of the feasibility of vaccine use in existing child and adult immunization programs. Feasibility issues include (but are not limited to) acceptability to the community, parents, and patients; vaccine distribution and storage; access to vaccine and vaccine administration; impact on the various health care delivery systems; population distribution effects; and social, legal, and ethical concerns.

2. *The antigen is effective in terms population based prevention.*

   In the clinical development of a vaccine, the efficacy of the vaccine is studied using FDA-approved research protocols that evaluate whether a vaccine protects individuals from contracting the disease in population-based studies or generates an immunologic response (immunogenicity) comparable to vaccines that have been shown to be effective in preventing disease. More information about its population-based effectiveness is gained from large trials and community-based analyses after FDA approval.

3. *The vaccine containing this antigen is cost effective (from a societal perspective).*

   Immunizations are the most cost-effective clinical preventive service for children, saving both lives and money. Vaccines may be cost effective without being cost saving. In other words, the direct costs of some vaccines (e.g. antigen, storage, administration) balanced against direct savings (e.g. medical care, disability, death) may not result in net savings. In some cases, societal or indirect costs (e.g. lost productivity of care takers of ill children) will also need to be taken into consideration. These costs are much harder to quantify. Not all vaccines recommended by the ACIP are cost saving or equally effective, so some determination of the vaccine's relative cost effectiveness may need to be made for comparison purposes when applying the criteria.

4. *Experience to date with the vaccine containing this antigen indicates that it is safe and has an acceptable level of side effects.*

   Vaccinations are not without side effects. Vaccine safety is evaluated using pre-release FDA-approved research protocols, but more safety data comes to light after release of the vaccine when it is used in larger groups of individuals. Health care providers are required by law to report certain adverse events, and any one may report any reaction or event thought to be related to receipt of a vaccine. These reports are entered into a national database, the Vaccine Adverse Events Reporting System (VAERS). The purpose of VAERS is to look for trends and pinpoint the need to investigate safety concerns further. The known risks associated with each vaccine (or antigen) must be balanced against the risks of the disease.

II. *Disease Burden Criteria*

5. *The vaccine containing this antigen prevents diseases with significant morbidity and/or mortality implications (in some sub-set of the population).*

   Vaccines have the potential to reduce, or in some cases even eliminate, diseases that can result in serious illness, long-term disability, or death. For example, before the measles immunization was available, nearly everyone in the United States contracted measles and an average of 450 measles-associated deaths were reported each year between 1953 and 1963. The morbidity/mortality burden of measles was not equal for all members of the population. Examples of significant morbidity measures include rates of hospitalizations, long-term disability, disease incidence, and disproportionate impact.

6. *Vaccinating the infant, child, or adolescent against this disease reduces the risk of person-to-person transmission.*

   Having a large percentage of the population vaccinated prevents the spread of infectious diseases. Even community members who are not vaccinated (such as newborns and those with chronic illnesses) are offered some protection because the disease has little opportunity to spread within the community. Vaccinating children in school and/or childcare centers can increase the percentage of children in these groups who are immune and thus reduce the risk of outbreaks of the disease in these groups and in the community at large.

III. *Implementation Criteria*

7. *The vaccine is acceptable to the medical community and enjoys a high degree of public trust.*

   It is possible to gauge the level of provider acceptance of a vaccine by querying state professional societies such as the Washington Academy of Family Physicians and the Washington State Chapter of the American Academy of Pediatrics. While there is generally a good correlation between the levels of physicians' and the general publics' acceptance of particular vaccines, a growing minority of the public has not accepted some recommended vaccines. Therefore, public acceptance of specific vaccines needs to be assessed. Most parents today have never seen a case of diphtheria, measles, or other once-common diseases now preventable by vaccines. As a result, some parents wonder why their children must receive shots for diseases which seemingly no longer exist in Washington communities. Myths and misinformation about vaccine safety abound and can make it difficult for parents who are trying to make sound decisions about their children's health care. A mandate for a vaccine with poor provider or public acceptance would likely be resisted. Postponing the regulation until there is greater approval of the vaccine would assure more effective policy.

8. *The administrative burdens of delivery and tracking of vaccines containing this (these) antigen(s) are reasonable.*

   Many players are involved in the implementation of a vaccine mandate, including: the Department of Health, the Department of Social and Health Services, the Office of Superintendent of Public Instruction (OSPI), local health jurisdictions, schools, health plans, and health care providers. For each of these key players, there are issues that affect the feasibility of implementing an immunization mandate. For example, the introduction of a new vaccine mandate can result in schools conducting more parental follow-up and making changes to record and information systems—this in turn can impact school staff workload. Assuring a reasonable burden of work will enhance the effectiveness of the policy. The TAG will consult with affected parties such as OSPI, schools and childcare centers when assessing an antigen against this criterion.

9. *The burden of compliance for the vaccine containing this antigen is reasonable for the parent/caregiver.*

   Parents and caregivers are often involved in obtaining vaccines for children. This can include: transporting children to medical appointments, taking time off of work for medical appointments, maintaining the child's immunization records, etc. When a vaccine is mandated, it affects the health decisions that parents make on their child's behalf because parents must, at the very least, take the mandated vaccine into account.